

UNITED STATES DISTRICT COURT  
DISTRICT OF MINNESOTA

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In re: BAIR HUGGER FORCED AIR  
WARMING DEVICES PRODUCTS  
LIABILITY LITIGATION

MDL No. 15-2666 (JNE/FLN)

This Document Relates To:  
All Actions

**DEFENDANTS' RESPONSE TO  
PLAINTIFFS' MOTION TO  
COMPEL DEFENDANTS TO  
PRODUCE DOCUMENTS  
SUPPORTING ANY CHALLENGES  
TO PLAINTIFFS' PROOF OF BAIR  
HUGGER USE IN BELLWETHER  
REPOPULATION**

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Plaintiffs' motion to compel and motion to strike Defendants' challenges to Plaintiffs' proof of Bair Hugger use in the bellwether repopulation pool should be denied because it is based upon a mischaracterization of Defendants' challenges and an improper attempt to shift Plaintiffs' burden of establishing product use to the Defendants.

**I. Defendants' Challenges Are Well Founded and Plaintiffs' Request That They Be Stricken is Baseless.**

The sole purpose of the bellwether selection process is to identify representative cases that can be worked up for trial. Of the five federal bellwether cases selected from the first group of 150 randomly-selected cases, only one case – *Gareis* – remains. Two of the five cases were voluntarily dismissed with prejudice only after case-specific discovery revealed that the Bair Hugger patient warming system was not used at all in the plaintiff's surgery (*Skaar*), or was not used for the duration of the plaintiff's surgery (*Kamke*). Because the information the Plaintiffs relied on to establish product use proved insufficient,

the Court is now requiring more. *See* DX1, 12/21/17 Status Conference Hearing Transcript, at 26:15-18.

Specifically, Pretrial Order No. 24 requires each plaintiff in the Second Bellwether Selection Group to provide proof of product use at the outset of the bellwether nomination process. While PTO No. 24 does not detail what proof is required, the order was not created in a vacuum. The Court explained the rationale for this requirement and detailed what purported proof is insufficient:

THE COURT: You now know because of the bellwether process that's gone through so far that there are a number of cases that are being brought by plaintiffs who do not have sufficient reason to know that they actually have a product that was involved in their surgery. That's just a very basic fact.

And we have allowed all of these cases to go forward on the simple check mark, and we now know that's not enough. And to say that 4500 cases should be allowed to proceed now based on a check mark when everybody knows that in reality that doesn't tell you anything is inconsistent with the fundamental requirement that there be some good faith belief on the part of the plaintiff that they've got a case before they bring it.

DX1, 12/21/17 Status Conference Hearing Transcript, at 28:14-29:2. Plaintiffs' position that Defendants' challenges are "clearly unwarranted" or "split hairs" is not only disingenuously removed from the above history out of which the requirement arose, but also reflects a misunderstanding of the spectrum across which Defendants' challenges fall. Defendants' challenges can be divided, generally, into the following categories:

Defendants' Challenges	Plaintiffs' Response	Number of Cases
Letter from provider affirms Bair Hugger system was not used	Fail to acknowledge the challenge or dismiss the case	1
No proof of warming of any kind	Fail to acknowledge the challenges or dismiss the cases	8
Discrepancy between the date of surgery at issue between the Complaint, the PFS, and/or the medical records; product use cannot be further evaluated until the discrepancy is resolved	The objection is irrelevant or the result of a “typographical error”	6
Medical records reference warming or forced-air warming, generally, but there is no mention of the Bair Hugger system specifically; some of these cases also lack recent product placement and/or blanket sales in the 12 months prior to the procedure at issue; no additional verification provided	Fail to acknowledge	15
Medical records reference Bair Hugger in a “check mark” or form document; some of these cases also lack recent product placement and/or blanket sales in the 12 months prior to the procedure at issue; no additional verification provided	Plaintiffs dispute Defendants' challenges in this category	15
Medical records reference what appears to be a Bair Hugger serial number, but product placement information does not show the corresponding serial number placed at the facility at issue	Plaintiffs dispute Defendants' challenges in this category	4
Other	Fail to acknowledge	4
<b>Total Challenges</b>		<b>53<sup>1</sup></b>

<sup>1</sup> On February 23, 2018, Plaintiffs submitted *Lexecon* waiver information for the 100 cases in the Second Bellwether Selection Group. As a result, 30 cases are excluded because the plaintiffs did not agree to execute a *Lexecon* waivers. Sixteen of the 53 cases that Defendants challenge are in this group of 30 and no longer at issue.

While Plaintiffs wage a wholesale attack on Defendants' challenges, they highlight only those cases where there is purported proof of product use, largely in the form of the "check mark" on a form – the exact type of purported proof the Court has said is insufficient. As to Defendants' other challenges, including cases without any evidence of Bair Hugger use, Plaintiffs entirely ignore the specifics of Defendants' challenges, yet maintain they should be stricken. Not only are Plaintiffs' objections unfounded since it is their burden to prove product use, but Plaintiffs also inexplicably continue to press forward on cases lacking *any* evidence of product use.

Finally, Defendants do not understand Plaintiffs' objection to the fact that Defendants' submission points out five cases in the Second Bellwether Selection Group that do not involve hip or knee procedures and therefore cannot proceed as bellwether cases. The entire purpose of this process is to arrive at cases that can be worked up for trial, and Defendants simply wish to avoid needlessly devoting resources to cases that cannot proceed as bellwether trial cases because they do not meet the representative criteria. Defendants request that Plaintiffs' motion to strike Defendants' challenges be denied. Further, cases for which product-use challenges remain should not be considered as bellwether trial candidates until the disputes are resolved.

## **II. Plaintiffs' Motion to Compel Additional and Unspecified Documents Should be Denied.**

In addition to requesting that Defendants' challenges be stricken, Plaintiffs vaguely demand that this Court order Defendants to comply with their production obligations under

PTO No. 24. Defendants have fully complied with those obligations, and there is nothing more for this Court to order Defendants to do.

To fulfill their obligations under PTO No. 24, Defendants produced detailed spreadsheets of data extracted from their electronic recordkeeping systems. First, Defendants produced data indicating dates that Bair Hugger warming units were placed at the hospitals where plaintiffs' surgeries allegedly occurred. Second, Defendants produced sales of Bair Hugger blankets to the same hospitals in the 12-month period before the alleged surgeries. Even though PTO No. 24 only requires Defendants to provide information relevant to their product-use challenges, Defendants produced these data for all cases where it was available, including those where Defendants do not challenge product use. Defendants produced exactly what the Court said was required. DX1, 12/21/17 Status Conference Hearing Transcript, at 31:2-5 ("So if you've got evidence like that [evidence that Defendants never sold Bair Hugger systems to the facility where the plaintiff's surgery was performed], that should be part of the give and take in putting together the process for repopulating the Bair Hugger bellwether list . . .").

As Defendants have explained to Plaintiffs in interrogatory responses, there are significant limitations on these data. The fact that a warming unit was delivered to a hospital, or that blankets were sold, does not confirm that the Bair Hugger system was in fact used in any specific plaintiff's surgery. As this Court previously acknowledged, it is, at most, an indication that the Bair Hugger system may have been available for use by the plaintiff's treaters.

MAGISTRATE JUDGE NOEL: And I think what Judge Erickson is saying is that that burden is more on the plaintiffs than on the defendants, and it's not really about the defendant's sales records or who they sell Bair Huggers to. It's about whether or not this plaintiff was exposed to the device that is alleged to have caused his damages. And I guess maybe I'm not understanding what the burden is or why that's a difficult thing for a plaintiff's lawyer to ascertain at the front end of a lawsuit.

DX1, 12/21/17 Status Conference Hearing Transcript, at 30:11-19.

Defendants' placement and sales data are no substitute for medical records that clearly and unambiguously indicate Bair Hugger use (and even medical records are an imperfect indication, as the parties have learned from the *Skaar* and *Kamke* bellwether cases), and/or direct confirmation from the hospital that the Bair Hugger system was in fact used.

Plaintiffs have also argued (in meet-and-confer correspondence, though not in their motion) that PTO No. 24 imposed an obligation on Defendants to search 3M's corporate ESI to determine whether there might be any email that sheds further light on whether the Bair Hugger system may have been used in a given plaintiff's case. Though it is extremely unlikely, it is theoretically possible that there could be such an email. But Defendants have absolutely no idea how they could possibly find it amongst the emails of the various employees of the Defendants who may have had contact with unspecified personnel at the hospitals at issue. The burden of any such effort would be grotesquely disproportionate to the benefit. That is especially so when the burden of establishing product use is on Plaintiffs, and their counsel can answer the question of Bair Hugger use simply by

contacting plaintiffs' medical providers and asking for confirmation – something that most of them have, inexplicably, failed to do.

Defendants respectfully request that Plaintiffs' motion be denied in its entirety. The Court's and the parties' resources should be devoted to analyzing those cases where product use has been established. Plaintiffs should be held to their burden of establishing that the fundamental threshold requirement to bringing suit in this MDL has been satisfied for each plaintiff, and their continued efforts to shift that burden to Defendants should be rejected.

Dated: February 27, 2018

Respectfully submitted,

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